

Application No. 08/499,423

REMARKS

I. PRELIMINARY REMARKS

Claims 1, 3-33, 35, 42-44, 46-69, 71-77, 79-88, and 91-97 are pending in the application. Claim 58 is amended to change its dependency in response to an objection in the previous Office Action. Claims 67-69 are now canceled as redundant due to the amendment to claim 58. Claims 35, 74, 82, 87, 88, 95 and 96 are amended to add an inadvertently omitted word; the dependency of claims 88 and 96 is correspondingly changed.

Claims 1, 3-5, 24-33, 35, 42-44, 46-69, 71, 72 and 79-85 are rejected under 35 USC 112, first paragraph as indefinite. Independent claims 1, 33 and 42 are amended in response to this rejection as are dependent claims 5-7 and 9. Claim 8 is canceled as redundant as a result of this amendment. Claims 70-73 are now cancelled. Claims 76, 80 and 84 are amended for clarity.

Claim 27 is amended herein in response to a 35 USC 112, second paragraph rejection. Claims 1-5, 24-26, 32-35 and 86-91 are newly rejected under 35 USC 102.

II. APPLICANTS' INVENTION

The present invention relates to a porous polytetrafluoroethylene tube covered by one or more layers of porous polytetrafluoroethylene film, wherein the film-covered tube circumferentially distends from an initial circumference upon the application of a circumferentially distending force such as applied by an internal pressure. The film-covered tube exhibits minimal recoil following the removal of the circumferentially distending force. The porous polytetrafluoroethylene film-covered tube preferably has a second circumference larger than the initial circumference (the second circumference achieved by circumferential distension by force) which remains substantially unchanged by further increasing force. The porous polytetrafluoroethylene film-covered tube itself provides the circumferential distensibility up to the limit, without need of additional plastically deformable components such as metal stents. It is useful as a liner for pipes and vessels, particularly those having irregular luminal surfaces to which the polymeric tube can smoothly conform. The inventive film-covered tube is particularly useful as a liner for both living and prosthetic blood vessels. The limiting second circumference is of particular value for applications of this type in that it can be used to prevent further undesirable dilatation of the blood vessel into which it is fitted.

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III. REJECTION OF CLAIMS 1, 3-5, 24-33, 35, 42-44, 46-69, 71, 72 AND 79-85 UNDER 35 USC 112, FIRST PARAGRAPH AS BEING INDEFINITE.

The Examiner states that these claims are indefinite because the specification requires that the second circumference of the porous PTFE tube is limited as the result of a layer of PTFE film.

Claims 67-69 are canceled herein. Independent claims are amended by the addition of a limitation requiring the PTFE film. Accordingly, the rejection is now overcome.

IV. REJECTION OF CLAIMS 27-30 UNDER 35 USC 112, SECOND PARAGRAPH AS BEING INDEFINITE.

The Examiner concludes that it is not clear if the recited tube is a liner within another structure or if the tube has a liner in it. Claim 27, from which claims 28-30 depend, is amended herein and as such should overcome the objection.

V. REJECTION OF CLAIMS 1, 3-5, 24-31, 33, 35, 86-88, 91 AND 95-97 UNDER 35 USC 102(e) AS BEING ANTICIPATED BY GOLDFARB, US 6,436,135.

The Examiner states with regard to the various rejected claims that Goldfarb discloses a PTFE tube that is fully capable of having its circumference increase with the application of blood pressure. This is clearly true, however the claims require that the inventive graft stabilizes in circumference (the second circumference) upon reaching a higher internal pressure, as clearly taught by the specification. The graft of Goldfarb is not capable of this subsequent circumferential stability (this graft is described in the present specification with regard to its unlimited circumferential distensibility and its recoiling to a smaller circumference following the removal of a distending force). Further, the Goldfarb graft does not have the outer covering of porous PTFE film as required by the claims as amended herein in response to the 35 USC 112 first paragraph rejection.

Regarding the use of "about" in claim 4 as being relative terminology, applicants note that the rejection in question is based on novelty and not on indefiniteness. Further, the use of about is entirely appropriate, particularly when it is considered that the subject matter is a porous material and thickness limitations are inherently limited in precision. The use of "about" has a long history in claim limitations and is well appreciated; see, for example, *Ex Parte Eastwood, Brindle and Kolb*, 163 USPQ 316 (PTO Bd. App. 1968).

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Regarding recoil (claim 91), the Examiner is correct that recoil is inherent in the tubes of the prior art. The claim relates to a tube showing less recoil than the recoil inherent in the prior art. Examples 2 and 3 of the instant specification teach in detail how the reduction in recoil is achieved. None of the cited references suggest any such method or result. Example 3 also describes the recoil inherent in the Goldfarb (Impra) tube; see p. 17, line 35 to p. 18, line 8.

VI. REJECTION OF CLAIMS 1, 3-17, 19-31, 33, 35, 42-44, 46-69, 71-77, 79-88, AND 91-97 UNDER 35 USC 102(a) AS BEING ANTICIPATED BY SHANNON et al., US 5,641,373.

This rejection appears based on the Examiner's conclusion that the limitation recited in Claim 1 of applying internal pressure up to a second circumference such that the tube "limits further growth in the second circumference to remain substantially unchanged" or in claim 33, "limits further growth to substantially the second circumference" fails to distinguish the expansion beyond the second circumference as being different from the first to second circumference expansion, and that therefore the claim language reads on a further expansion up to the second circumference.

Applicants respectfully disagree with the Examiner's position, rather the claims are clear with regard to the different behavior of the tube following further increasing pressure beyond that necessary to increase the circumference from the first circumference to the second, larger circumference. Both claims 1 and 33 specify a change from the first circumference to the second circumference results from the application of increasing internal pressure, and that *further increasing pressure* results in the tube remaining at substantially the same, second circumference. The specification clearly supports this behavior, teaching in detail how the ePTFE tubes of the prior are subjected to additional process steps that result in the new behavior (see, for example, the manufacturing flow chart of Figure 4).

Regarding the claims relating to the *lack* of recoil in the inventive tubes, as noted above, this recoil behavior is indeed inherent in the tubes of the prior art. The lack of recoil is of great value in a tube that is intended to be expanded in circumference until it resides in full contact with the luminal surface of another tubular form (such as a blood vessel) against which it has been expanded. If such a tube were to recoil appreciably once the distending force was removed, it would be at risk of losing its full contact with the outer tubular form, and vulnerable to moving from the position to which it had been fitted during the flow of fluid through the distended tube. The lack of recoil is thus of great value for such applications where an ePTFE tube is fitted as a liner within another tubular structure. With regard to the claimed range of minimal recoil being 7% or less, the Examiner notes that a tube expanded in circumference only 5% would inherently recoil

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less than 7%. Applicants point out that recoil is measured as clearly taught in the specification by increasing the circumference (and consequently the diameter) of the tube by at least 25% before measuring the amount of recoil. This is described in detail at page 8, lines 4-27.

VII. REJECTION OF CLAIM 18 UNDER 35 USC 103(a) AS UNPATENTABLE OVER SHANNON et al., US 5,641,373 IN VIEW OF HUGHES et al., US 4,728,328, AND CLAIM 32 AS UNPATENTABLE OVER GOLDFARB, US 6,436,135 IN VIEW OF HUGHES et al., US 4,728,328.

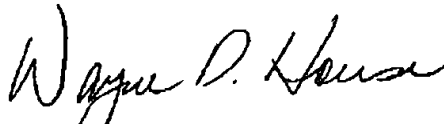
Goldfarb and Shannon et al. are addressed above; Hughes et al. only add the disclosure of a graft having three ends (bifurcated). Claims 18 and 32, as ultimately dependent to claim 1, are patentable as argued above.

VIII. REJECTION OF CLAIMS 42-44, 46-50, 52-56, 58-62, 64-68, 71-77, 79-85 AND 92-94 UNDER 35 USC 103(a) AS BEING UNPATENTABLE OVER GOLDFARB, US 6,436,135.

As described above, the property of excessive recoil is inherent in the ePTFE tube described by Goldfarb; note, again, the description of the recoil of this tube (used as a comparative control) in Example 3 (p. 17, line 35 to p. 18, line 8). Likewise, the value of a lack of recoil has also been described above. Goldfarb clearly does not teach or suggest either a graft having a lack of recoil or any method by which such an article might be achieved.

The applicants believe that their claims are in good and proper form and are patentable over the cited art. As such, the applicants respectfully request reconsideration, allowance of the claims and passage of the case to issuance.

Respectfully submitted,



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